

**REMARKS**

Applicants respectfully request reconsideration of the rejections set forth in the Final Office Action mailed on May 12, 2008.

Claims 8-9 and 22-24 had been pending and were examined. Claims 1-7 and 10-21 were previously cancelled without prejudice or disclaimer. Claims 22 and 23 have been cancelled in this amendment without prejudice or disclaimer. Applicants reserve the right to pursue the cancelled subject matter in future applications. Pending entry of this amendment, claims 8-9 and 24 have been amended. Thus, with this amendment, claims 8-9 and 24 are pending.

Claims 8 and 9 have been amended to recite steps:

- d) bringing into contact a mesangial cell that expresses the EDG-2 receptor and the lysophosphatidic acid and measuring mesangial cell growth;
- e) bringing into contact a mesangial cell that expresses the EDG-2 receptor, lysophosphatidic acid, and the test compound of step c) determined to change the binding property of the lysophosphatidic acid and the EDG-2 receptor and measuring mesangial cell growth;
- f) measuring the effect of the test compound on mesangial cell growth by comparing d) and e); and
- g) determining whether the test compound inhibits mesangial cell growth.

Support for that amendment is found in the specification, for example, at least at page 8, line 29 to page 9, line 19; page 35, lines 9-16; and page 36, lines 13-16.

Claim 9 has also been amended to indicate that the kit comprises “lysophosphatidic acid, an assay buffer, and instructions.” Support for that amendment is found in the specification, for example, at least at page 8, lines 29-32 and page 39, line 16 to page 40, line 22.

Claim 24 has been amended to recite “administering a test compound that changes the binding property of the lysophosphatidic acid and the EDG2 receptor and that inhibits mesangial

cell growth to a test animal" and "determining whether the test compound improves a condition of diabetic nephropathy, chronic renal failure, nephritis, glomerulonephritis, interstitial renal disease or renal edema." Support for that amendment is found in the specification, for example, at least at page 60, lines 6-11.

Accordingly, the amendments are fully supported by the specification as filed. Upon entry of the present amendments, claims 8-9 and 24 will be under consideration.

Applicants address below each issue raised in the Final Office Action of May 12, 2008.

#### **Preliminary Matters**

Applicants thank the Examiner for the interview on April 25, 2008. During the interview, the Examiner stated that the Final Office Action mailed January 24, 2008, would be vacated and a new Office Action would be issued with a new statutory period for response.

Applicants note with appreciation that the Examiner has withdrawn the rejections of claims 8 and 9 under 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 112, second paragraph. *See Action at page 2.*

#### **Claim Rejections**

##### **I. Rejection of claims 8-9 and 22-24 under 35 U.S.C. § 112, Second Paragraph**

Claims 8-9 and 22-24 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claiming the subject matter which applicant regards as the invention. Specifically, the Examiner stated that the "claims are indefinite because they do not refer back to the preamble." Action at page 3.

Applicants respectfully disagree. The claims do refer back to the preamble. The preamble of claim 8, for example, recites a "method of screening for a test compound or a salt thereof that changes a binding property of lysophosphatidic acid or a salt thereof to an EDG-2

receptor or a salt thereof and that inhibits mesangial cell growth . . . ." The body of the claim recites:

- a) bringing into contact the lysophosphatidic acid, the EDG-2 receptor, and the test compound;
- b) measuring the binding property of the lysophosphatidic acid and the EDG-2 receptor;
- c) determining whether the test compound changes the binding property of the lysophosphatidic acid and the EDG-2 receptor;
- d) bringing into contact a mesangial cell that expresses the EDG-2 receptor and the lysophosphatidic acid and measuring mesangial cell growth;
- e) bringing into contact a mesangial cell that expresses the EDG-2 receptor, lysophosphatidic acid, and the test compound of step c) determined to change the binding property of the lysophosphatidic acid and the EDG-2 receptor and measuring mesangial cell growth;
- f) measuring the effect of the test compound on mesangial cell growth by comparing d) and e); and
- g) determining whether the test compound inhibits mesangial cell growth.

Thus, the body of the claim refers back to the preamble.

The Examiner also stated that it is "unclear if the amino acid sequence which is 95% homologous to Seq. Id. No. : 1 still maintains the requirement of binding the lysophosphatidic ligand." Action at page 3.

Applicants respectfully disagree. Nonetheless, the claims have been amended to delete the phrase "an amino acid sequence with at least 95% homology to the amino acid sequence of SEQ ID NO:1." Accordingly, this rejection is moot.

Regarding claim 9, the Examiner contended that the metes and bounds of the claim are unclear alleging that claim 9 is "an incomplete kit claim since it does not designate the components of the kit and the relationship between them." Action at page 3.

Applicants respectfully traverse. As amended, claim 9 recites components of the kit.

The Examiner also rejected claim 24 contending that “[t]here are no method steps disclosed that are to be taken to determine if the test compound identified in the previous method is useful for treating the conditions claimed.” Action at page 3. The Examiner concluded that “the claim is just a mental step and not a method claim.” *Id.*

Applicants respectfully traverse. Claim 24 is not a “mental step” as alleged by the Examiner. Instead, claim 24 requires “administering the test compound that changes the binding property of the lysophosphatidic acid and the EDG2 receptor and that inhibits mesangial cell growth to a test animal” and “determining whether the test compound improves a condition of diabetic nephropathy, chronic renal failure, nephritis, glomerulonephritis, interstitial renal disease or renal edema.” Thus, claim 24 does recite method steps.

For at least these reasons, Applicants respectfully request withdrawal of the rejections.

**II. Rejection of Claims 8-9 and 22-24 under 35 U.S.C. § 102(b)**

Claims 8-9 and 22-24 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Erickson et al. (U.S. Patent 6,485,922). Reiterating the reasoning of the previous Office Action, the Examiner concluded that “the test performed by Erikson et al. would identify compounds that modulate the activity of EDG receptors.” Action at page 5. The Examiner contended that “[i]nhibiting proliferation of mesangial cells by antagonistic action of a compound binding to EDG-2 receptor is linked to signal transduction events which occur in all cells expressing the receptor and is not unique to mesangial cells.” *Id.* Furthermore, the Examiner alleged that “step d) of the method of screening is not considered an actual method step since it is just a mental step and is not given patentable weight.” *Id.* Regarding claims 9

and 23, the Examiner stated that “the reagents that are claimed as a part of [a] kit would inherently meet the limitations [of Erickson].” *Id.*

Applicants respectfully traverse. According to the M.P.E.P., “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” M.P.E.P. § 2131 (citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987)). Erickson does not teach each and every element of the instant claims. Contrary to the Examiner’s contentions, step g) (previously step d)) is not a mental step. Step g) requires the active steps of d) – f), which recite:

- d) bringing into contact a mesangial cell that expresses the EDG-2 receptor and the lysophosphatidic acid and measuring mesangial cell growth;
- e) bringing into contact a mesangial cell that expresses the EDG-2 receptor, lysophosphatidic acid, and the test compound of step c) determined to change the binding property of the lysophosphatidic acid and the EDG-2 receptor and measuring mesangial cell growth;
- f) measuring the effect of the test compound on mesangial cell growth by comparing d) and e).

In contrast, Erickson does not teach these elements and therefore, Erickson does not anticipate the instant claims. Applicants respectfully request withdrawal of the rejection.

#### **IV. Rejection of Claims 8-9 and 22-24 under 35 U.S.C. § 102(e)**

Claims 8-9 and 22-24 were rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Miller et al. (U.S. Patent 6,875,757). According to the Examiner, “[i]nhibiting proliferation of mesangial cells by antagonistic action of a compound binding to [the] EDG-2 receptor is linked to signal transduction events which occur in all cells expressing the receptor and is not unique to mesangial cells.” Action at page 6. The Examiner again urged that “step d)

of the method of screening is not considered an actual method step since it is just a mental step and is not given patentable weight.” *Id.*

Applicants respectfully traverse. As noted above, step g) (previously step d)) is not a mental step because it requires the active steps of d) – f), which recite:

- d) bringing into contact a mesangial cell that expresses the EDG-2 receptor and the lysophosphatidic acid and measuring mesangial cell growth;
- e) bringing into contact a mesangial cell that expresses the EDG-2 receptor, lysophosphatidic acid, and the test compound of step c) determined to change the binding property of the lysophosphatidic acid and the EDG-2 receptor and measuring mesangial cell growth;
- f) measuring the effect of the test compound on mesangial cell growth by comparing d) and e).

As discussed above, Miller does not teach a step of contacting a mesangial cell with a test compound and measuring mesangial cell growth, or a kit instructing such steps. Thus, Miller does not anticipate the instant claims. Accordingly, Applicants respectfully request withdrawal of the rejection.

#### V. Conclusion

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing claims 8-9 and 24 in condition for allowance.

It is respectfully submitted that the entry of the Amendment would allow the Applicants to reply to the final rejections and place the application in condition for allowance.

Finally, Applicants submit that the entry of the amendment would place the application in better form for appeal, should the Examiner dispute the patentability of the pending claims.

Please grant any further extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: July 14, 2008

By: Yuko Soneoka  
Yuko Soneoka  
Reg. No. 60,018  
Customer No. 22,852